

)	MDL No. 1456
In re: PHARMACEUTICAL INDUSTRY)	Master File No. 01-12257-PBS
AVERAGE WHOLESALE PRICE LITIGATION)	Subcategory Case No. 06-11337
)	
)	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO:)	
)	Magistrate Judge
)	Marianne B. Bowler
<i>State of California ex rel. Ven-A-Care of the Florida</i>)	
<i>Keys, Inc. v. Abbott Labs, Inc. et al.,</i>)	
Civil Action No. 03-11226-PBS)	
)	

Pursuant to Rule 56.1 of the Local Rules of this Court, Defendant Sandoz Inc. (“Sandoz”) hereby submits this Response to Plaintiffs’ Local Rule 56.1 Statement of Undisputed Facts as to Sandoz Inc. in support of their Motion for Partial Summary Judgment.

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Furthermore, Sandoz does not respond to the headings contained in Plaintiffs' Statement of Undisputed Material Facts as to Sandoz, and objects to such headings to the extent that they purport to state or characterize facts as such facts or characterizations are not properly supported with citations to the record. To the extent a response is required, Sandoz disputes any facts or characterizations contained in these headings. Sandoz leaves such headings and titles in this Response solely for the Court's convenience.

PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO DEFENDANT SANDOZ INC.

- A. Medi-Cal Pharmacy Providers Submitted Claims for the Relevant Sandoz Drugs Which Were Paid By Medi-Cal with Government Funds Based on AWP's Reported by FDB.
1. During the period from 1994 through 2004, pharmacies and other Medi-Cal providers routinely submitted pharmaceutical claims to Medi-Cal (through its fiscal intermediary, EDS) for reimbursement of the Sandoz drugs at issue in this action (the "Subject Drugs") that those providers had dispensed to program beneficiaries. (Declaration of Nicholas N. Paul in Support of Motion for Partial Summary Judgment (hereinafter, "Paul") Ex. 1 (Gorospe Decl.), at ¶¶ 3, 4.)

SANDOZ' RESPONSE TO PARAGRAPH 1:

Sandoz does not dispute that providers submitted pharmaceutical claims to Medi-Cal for reimbursement of drugs those providers had dispensed to program beneficiaries. Sandoz further states that the reimbursement claims contained the providers' usual and customary charge to the general public. *See* Declaration of Catherine Castaldo in Support of Sandoz Inc.'s Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Facts as to Sandoz Inc. ("Castaldo Decl."), Ex. 1 (Excerpts of September 22, 2008 deposition of J. Kevin Gorospe ("09/22/08 Gorospe Dep."), at 689:5-692:10). Sandoz however disputes Paragraph 1 on the grounds that the declaration of J. Kevin Gorospe refers generally to all defendants in this action and all the Subject Drugs and does not refer specifically to Sandoz or Sandoz' drugs.

2. Medi-Cal paid those claims (through EDS) with Government funds. (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 3, 4.)

SANDOZ' RESPONSE TO PARAGRAPH 2:

Sandoz disputes Paragraph 2 on the grounds that the term “Government funds” is vague, ambiguous, undefined and susceptible to more than one interpretation. Sandoz further states that, throughout the relevant time period, at least 50% of each claim at issue was paid with funds provided by the federal government. *See* 42 U.S.C.A. § 1396d(b) (2009).

3. Pursuant to applicable statutory and regulatory requirements, the claims were adjudicated and paid *at the lesser of* the provider’s usual and customary charge or at the Cost of the Drug Product plus a dispensing fee. By statute, the total payment was then reduced by an amount varying over time from \$.10 to \$.50 per claim. (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5a, 5b, 6.)

SANDOZ' RESPONSE TO PARAGRAPH 3:

Sandoz disputes Paragraph 3 on the grounds that California was never limited to paying no more than the cost of a drug on a drug-by-drug basis. Rather, for drugs subject to a Federal Upper Limit (“FUL”), federal regulations merely limited payment in the aggregate, across all drugs, to the amount that would result from the application of the FUL plus a reasonable dispensing fee. *See* Castaldo Decl., Ex. 2. For all “other drugs” not subject to a FUL, a state agency’s payment “must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the (1) Estimated Acquisition Cost (“EAC”) plus reasonable dispensing fees established by the agency or (2) providers’ usual and customary charges to the general public.” *See* 42 C.F.R. § 447.512(b) (2009). The regulations define “estimated acquisition cost” to be a state agency’s “best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.” *See* 42 C.F.R. § 447.502 (2009). Within these guidelines, California had broad discretion to set its reimbursement methodology as it saw fit,

see Castaldo Decl., Ex. 3 at 431:4-9; Castaldo Decl., Ex. 4 at HHC002-0565; Castaldo Decl., Ex. 5 at 433:8-449:12; Castaldo Decl., Ex. 6 at 209:11-210:15, subject only to the requirement that its payments were consistent with efficiency, economy, and access to quality care. See Joint SOF at ¶¶ 14, 52, 56, 57¹; see also Castaldo Decl., Ex. 7 at 108:3-109:13; Castaldo Decl., Ex. 8 at 307:13-308:5; Castaldo Decl., Ex. 9 at 464:2-465:7; Castaldo Decl., Ex. 10 at 49:10-51:18. Sandoz further refers the Court to statutes and regulations governing California’s reimbursement methodology as the best evidence of Medi-Cal’s reimbursement methodology during the relevant time period.

4. The Cost of the Drug Product was set at *the lowest of* the drug’s Estimated Acquisition Cost (“EAC”), the Federal Allowable Cost (FAC, a/k/a FUL), or (c) the Maximum Allowable Ingredient Cost (MAIC). (Paul Ex. 1 (Gorospe Decl.), at ¶ 5a, 5b.)

SANDOZ’ RESPONSE TO PARAGRAPH 4:

Sandoz does not dispute that, throughout the relevant time period, Medi-Cal reimbursed pharmacists and other Medicaid providers who dispensed the Subject Drugs at the lower of EAC, the FUL, the Maximum Allowable Ingredient Cost (“MAIC”), or the charge submitted by the provider. See Joint SOF at ¶ 18; Castaldo Decl., Ex. 11. Sandoz further refers the Court to statutes and regulations governing California’s reimbursement methodology as the best evidence of Medi-Cal’s reimbursement methodology during the relevant time period.

Sandoz otherwise disputes Paragraph 4 on the grounds that California never intended payments based on EAC, FUL, or MAIC to approximate providers’ actual “Cost for the Drug Product” on a drug-by-drug basis. See, e.g., Castaldo Decl. Ex. 12 (Excerpts of June 11, 2007 deposition of Kevin Galownia (“06/11/07 Galownia Dep.”) at 113:6-9; 114:6-9; 220:16-221:2). Sandoz adopts herein its response to Paragraph 3 and further states that, consistent with the

¹ “Joint SOF at ¶ __” refers to the Defendants’ Joint Statement of Undisputed Material Facts in Support of Their Motions for Partial Summary Judgment, Dkt. No. 6703.

flexibility afforded by the federal regulations, California adopted reimbursement methodologies that it knew would pay providers more than their actual acquisition costs, particularly for generic drugs, for its own policy reasons. For instance, when it adopted the 1987 federal FUL regulations, California noted with approval that it would pay a “spread” of more than 100 percent for a generic drug and considered this a benefit for the Medi-Cal program, because it would promote the use of lower-cost generics. *See* Joint SOF at ¶ 26. During the late 1990s and early 2000s, California considered multiple proposals to reduce reimbursement payments to levels that would be closer to what providers paid to acquire drugs, but never adopted these proposals, citing concerns that the reduced payments would limit Medi-Cal beneficiaries’ access to care. *See* Joint SOF at ¶¶ 33, 35, 36. When California did revise its reimbursement methodology, first in 2002 and again in 2004, it made only modest reductions to reimbursement payments and acknowledged that its payments for generic drugs still significantly exceeded providers’ acquisition costs. *See* Joint SOF at ¶¶ 51-59.

5. The Estimated Acquisition Cost for the Subject Drugs was determined at all relevant times at the AWP reported by First Data Bank (“FDB”) less a discount of either 5% (from 1994 through October 2002), 10% (from November 2002 through August 2004), or 17% (August 2004 through December 2004). (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5b, 7.)

SANDOZ’ RESPONSE TO PARAGRAPH 5:

Sandoz does not dispute that California used these formulas to calculate EAC for reimbursement purposes but states that the underlying statutes and regulations are the best evidence of California’s reimbursement methodology. Sandoz further states that EAC would be used to calculate reimbursement only when the EAC plus the dispensing fee resulting payment would be lower than the usual and customary charge submitted by the provider, assuming there is no FUL or MAIC. *See* Castaldo Decl. Ex. 1 (09/22/08 Gorospe Dep. at 689:5-692:10.)

- B. Sandoz Set and Reported AWP for Its Products Without Regard to The Actual Prices Being Generally and Currently Paid By Providers.
6. Throughout the relevant time period, Sandoz set AWP for its products and reported those prices to pricing compendia, including FDB. (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 349:11-20.)

SANDOZ' RESPONSE TO PARAGRAPH 6:

Disputed as incomplete. The evidence shows that Sandoz set AWP for its products and provided these AWP to the pricing compendia, including First DataBank, for the relevant time period in accordance with its understanding of the use of the term in the industry, and that Sandoz AWP were not in any way false, deceptive, or misleading. *See, e.g.*, Castaldo Decl. Ex. 13 (Excerpt of August 23, 2007 deposition of Christopher Worrell (“08/23/2007 Worrell Dep.”) at 183:5-23); Castaldo Decl. Ex. 12 (06/11/2007 Galownia Dep. at 98:11-99:10; 159:13-21); Castaldo Decl. Ex. 14 (Excerpts of January 25, 2007 deposition of Hector Armando Kellum (“01/25/2007 Kellum Dep.”) at 37:5-13; 64:22-65:5). These AWP were not intended to be actual average prices by Sandoz, and were not understood to be actual average prices by First DataBank or California. *See, e.g.*, Castaldo Decl. Ex. 12 (06/11/2007 Galownia Dep. at 113:6-9; 114:6-9; 220:16-221:2). Indeed, Sandoz’ representatives attended numerous meetings with officials from Medi-Cal and believed that those officials all understood that AWP were not actual averages. *See* Castaldo Decl. Ex. 15 (Excerpt of May 6, 2009 deposition of Ronald H. Hartmann, R.Ph. (“05/06/2009 Hartmann Dep.”) at 337:16-341:12). Furthermore, when collecting AWP, First DataBank never told Sandoz that it was expecting actual average prices. *See* Castaldo Decl. Ex. 12 (06/11/2007 Galownia Dep. at 387:15-388:6). In fact, First DataBank told its own customers that AWP was referred to as “ain’t what’s paid.” *See* Castaldo Decl. Ex. 16 (Excerpt of July 20, 2009 deposition of Lynn Donovan (“07/20/09 Donovan Dep.”) at 355:5-20; Castaldo Decl. Ex. 17 (Donovan Ex. 15 (First DataBank Presentation re: Pricing

Methodologies), Bates # HI_HI000002693), Castaldo Decl. Ex. 18 (Excerpt of August 27, 2007 deposition of Patricia Kay Morgan (“08/27/2007 Morgan Dep.”) at 80:11-81:9).

7. At the time Sandoz launched a new product, there was no predictable relationship between the AWP Sandoz set for that product and the price at which Sandoz actually sold that product. (Paul Ex. 3 (6/11/07 Kevin Galownia Dep.), at 169:5-17.)

SANDOZ’ RESPONSE TO PARAGRAPH 7:

Disputed as incomplete. It is undisputed that Sandoz set AWP for its products and provided these AWP to the pricing compendia, including First DataBank, for the relevant time period in accordance with its understanding of the use of the term in the industry, and that Sandoz AWP were not in any way false, deceptive, or misleading. *See, e.g.*, Castaldo Decl. Ex. 13 (08/23/2007 Worrell Dep. at 183:5-23). These AWP were not intended to be actual average prices by Sandoz, and were not understood to be actual average prices by First DataBank or California. *See, e.g.*, Castaldo Decl. Ex. 12 (06/11/2007 Galownia Dep. at 113:6-9; 114:6-9; 220:16-221:2). Indeed, Sandoz’ representatives attended numerous meetings with officials from Medi-Cal and believed that those officials all understood that AWP were not actual averages. *See* Castaldo Decl. Ex. 15 (05/06/2009 Hartmann Dep. at 337:16-341:12). Furthermore, when collecting AWP, First DataBank never told Sandoz that it was expecting actual average prices. *See* Castaldo Decl. Ex. 12 (06/11/2007 Galownia Dep. at 387:15-388:6). In fact, First DataBank told its own customers that AWP was referred to as “ain’t what’s paid.” *See* Castaldo Decl. Ex.16 (07/20/2009 Donovan Dep. at 355:5-20; Castaldo Decl. Ex. 17 (Donovan Ex. 15 (First DataBank Presentation re: Pricing Methodologies), Bates # HI_HI000002693).

During the relevant time period, Sandoz reported its WACs simultaneously with its AWP to the pricing compendia when it launched a new product. *See* Castaldo Decl. Ex. 13 (08/23/2007 Worrell Dep. at 82:5-20); Castaldo Decl. Ex. 19 (Excerpt of June 19, 2008

deposition of Kevin Galownia (“06/19/08 Galownia Dep.”) at 68:6-10). Sandoz’ WAC is and always has been a real transaction price in the marketplace at the point of sale as it represents the price that the wholesaler is ultimately responsible for paying. It is the invoice price to wholesalers, and is the price that the wholesaler is ultimately responsible for paying, absent a discount or rebate. *See* Castaldo Decl. Ex. 13 (08/23/2007 Worrell Dep. at 82:5-17). Consistent with expectations in the marketplace, Sandoz’ AWP’s were always higher than its WACs. *See* Castaldo Decl. Ex. 12 (06/11/2007 Galownia Dep. at 165:4-6); Castaldo Decl. Ex. 20 (Morgan Ex. 13 (First DataBank Presentation, 2005 Customer Seminar), Bates # FDB-ALABAMA 087415). Sandoz often reduces its WACs as pricing erodes in the marketplace based on competition. *See* Castaldo Decl. Ex. 13 (08/23/2007 Worrell Dep. at 218:17-220:5).

8. When it was the first company to market and sell a particular generic product, Sandoz generally set and reported as an AWP for that particular product a price 10 to 20 percent below the AWP for the corresponding brand product, regardless of the price at which Sandoz actually sold that product. (Paul Ex. 3 (6/11/07 Kevin Galownia Dep.), at 162:14-20, 169:5-9; Paul Ex. 4 (1/25/07 Armando Kellum Dep.), at 79:1-14.)

SANDOZ’ RESPONSE TO PARAGRAPH 8:

Undisputed that when it was the first company to market and sell a particular generic product, Sandoz generally set and reported as an AWP for that particular product, a price at least 10% below the AWP for the corresponding brand. Sandoz also set and reported a WAC at launch. *See* Sandoz response to paragraph 7; *See also* Castaldo Decl. Ex. 14 (01/25/2007 Kellum Dep. at 80:11-14). Sandoz may be able to sell the product at launch for WAC, or market conditions may force it to provide discounts to some customers. *See* Castaldo Decl. Ex. 14 (01/25/2007 Kellum Dep. at 80:15-81:3). AWP indirectly affects selling prices because, based on the system in place in the industry, certain relationships are expected between AWP and WAC and contract prices,

and setting an AWP too low would reduce pricing flexibility. *See* Castaldo Decl. Ex. 14 (01/25/2007 Kellum Dep. at 163:19-167:22).

9. When Sandoz launched a product and there was already a competitive generic product on the market, Sandoz set its AWP by reference to the competitor's AWP. (Paul Ex. 5 (6/19/08 Kevin Galownia Dep.), at 70:19-71:11.)

SANDOZ' RESPONSE TO PARAGRAPH 9:

Disputed only to the extent the statement is read as an absolute rule instead of a general practice, as the only cited testimony is from a witness who was employed by Sandoz from 2002 to 2005. *See* Castaldo Decl. Ex. 19 (06/19/08 Galownia Dep. at 32:9-11; 34:12-13).

10. Sandoz knew that the generic market was very competitive (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 469:22-470:2) and that market prices for generic drugs tended to decline significantly after additional participants entered the market. (Paul Ex. 4 (1/25/07 Armando Kellum Dep.), at 87:20-88:7.)

SANDOZ' RESPONSE TO PARAGRAPH 10:

Undisputed, except Sandoz disputes any inference that market prices always declined, because in some instances they increased. *See, e.g.,* Castaldo Decl. Ex. 21 (Excerpt of March 26, 2008 deposition of Christopher Worrell ("03/26/08 Worrell Dep.") at 472:23); Castaldo Decl. Ex. 13 (08/23/2007 Worrell Dep. at 107:11-22).

11. Sandoz generally did not change its reported AWP in response to changes in transaction prices for its complaint products. Its practice was to set a product's AWP at launch and not change that AWP. (Paul Ex. 3 (6/11/07 Kevin Galownia Dep.), at 183:9-14; (Paul Ex. (3/26/08 Christopher Worrell Dep.), at 467:21-468:7.)

SANDOZ' RESPONSE TO PARAGRAPH 11:

Disputed. Both Mr. Galownia and Mr. Worrell testified that Sandoz set its AWP in accordance with its understanding of industry practice in order to obtain a generic designation and that AWP were not understood in the marketplace to be nor intended by Sandoz to be mathematical averages of transaction prices. *See* Castaldo Decl. Ex. 19 (06/19/2008 Galownia

Dep. at 72:8-21); Castaldo Decl. Ex. 21 (03/26/2008 Worrell Dep. at 383:21-384:9). Sandoz consequently generally did not change its reported AWP. AWP could be adjusted in instances in which Sandoz' product no longer was coded as generic or in instances in which there was "a change in the market condition that resulted in contract pricing that would essentially make it necessary to raise AWP to have the AWP higher than the contract price," Castaldo Decl. Ex. 19 (06/19/08 Galownia Dep. at 58:2-16); Castaldo Decl. Ex. 12 (06/11/2007 Galownia Dep. at 183:18-184:10).

12. On occasion, Sandoz raised the AWP for a product. (Paul Ex. 5 (6/19/08 Kevin Galownia Dep.), at 57:20-58:1.) Since Sandoz did not actually sell its products at AWP, (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 510:5-8), the only reason for raising its AWP was to increase the reimbursement spread. (Paul Ex. 5 (6/19/08 Kevin Galownia Dep.), at 58:2-16.)

SANDOZ' RESPONSE TO PARAGRAPH 12:

Disputed in part. Undisputed that Sandoz raised its AWP on occasion (see response to paragraph 11), and that Sandoz did not sell its products at AWP. The cited evidence does not support the last phrase, as Mr. Galownia testified specifically that the "main reason" to raise and AWP would be if there had been "a change in the market condition that resulted in contract pricing that would essentially make it necessary to raise AWP to have the AWP higher than the contract price." Castaldo Decl. Ex. 19 (06/19/08 Galownia Dep. at 58:2-16).

13. Sandoz was aware that it was necessary to report AWP to the pricing compendia in order for its products to be reimbursed by third party payers, such as Medi-Cal. (Paul Ex. 4 (1/25/07 Armando Kellum Dep.), at 46:18-47:11; Paul Ex. 5 (6/19/08 Kevin Galownia Dep.), at 72:8-21.)

SANDOZ' RESPONSE TO PARAGRAPH 13:

Sandoz disputes Paragraph 13 to the extent that it mischaracterizes Mr. Kellum's and Mr. Galownia's testimony regarding the reporting of AWP to First DataBank as necessary in order to be reimbursed by third party payers, including Medi-Cal. In fact, Mr. Kellum, a Sandoz Rule

30(b)(6) witness, testified that reporting AWP to pricing compendia in order to be reimbursed by third party payers “was never discussed as a reason” at Sandoz, and at no time testified that such a practice was “necessary.” *See* Castaldo Decl. Ex. 14 (01/25/07 Kellum Dep. at 46:18-47:11). Furthermore, Mr. Galownia testified that the reason that Sandoz reported AWP to pricing compendia was because it “was a requirement to get a generic designation.” *See* Castaldo Decl. Ex. 19 (06/19/08 Galownia Dep. at 72:8-21). Sandoz also disputes Paragraph 13 to the extent that Plaintiffs have failed to provide an evidentiary basis for the time period outside of Mr. Galownia’s employment with Sandoz.

14. FDB published the suggested AWP reported by Sandoz as the AWP for Sandoz’s products. (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 358:13-359:1.)

SANDOZ’ RESPONSE TO PARAGRAPH 14:

Sandoz disputes Paragraph 14, as First DataBank witnesses and documents show that First DataBank set and controlled the Blue Book AWP (“BBAWP”) field in the First DataBank database, and represented that BBAWPs were set based on wholesaler surveys. *See* Castaldo Decl. Ex. 18 (08/27/07 Morgan Dep. at 38:1-39:3; 42:10-43:7). First DataBank included AWP provided by manufacturers in the “SWP” or Suggested Wholesale Price field in the First DataBank database, and FDB did not represent that these were transaction prices. *See* Castaldo Decl. Ex. 18 (08/27/07 Morgan Dep. at 45:2-5). Mr. Hector Armando Kellum, a Sandoz Rule 30(b)(6) witness, testified that in certain instances there were discrepancies between the AWP submitted by Sandoz to First DataBank and what First DataBank published. *See* Castaldo Decl. Ex. 14 (01/25/07 Kellum Dep. at 56:4-12); Castaldo Decl. Ex. 18 (08/27/07 Morgan Dep. at 38:1-39:3, 42:10-43:7). Sandoz further disputes that the evidence cited by Plaintiffs represents Sandoz’ understanding regarding First DataBank’s practices throughout the relevant time period,

as Mr. Worrell was employed by Sandoz from 2002 to 2005. *See* Castaldo Decl. Ex. 21 (03/26/2008 Worrell Dep. at 311:4-7).

C. Sandoz Was Aware of the Prices Providers Paid For Its Products.

15. Sandoz maintained databases through which it regularly tracked the prices at which its products were being sold. (Paul Ex. 6 (1/27/09 Frank Stiefel Dep.), at 378:17-379:18.)

SANDOZ' RESPONSE TO PARAGRAPH 15:

Sandoz disputes Paragraph 15 as misleading and incomplete. Sandoz does not dispute that it knew the invoice prices (but not necessarily the final net prices, after including rebates and/or other credits) customers paid to Sandoz, and that such prices were different than the AWP's Sandoz provided to First DataBank. However, Sandoz disputes the implication that it was aware of the price paid by retail pharmacies that did not purchase directly from Sandoz. *See* Castaldo Decl. Ex. 21 (03/26/08 Worrell Dep. at 383:3-5; 401:12-17); Castaldo Decl. Ex. 22 (Excerpt of September 29, 2009 deposition of Christopher Worrell ("09/29/09 Worrell Dep.") at 326:4-9); Castaldo Decl. Ex. 12 (06/11/07 Galownia Dep. at 234:4-11; 241:4-6). Sandoz further disputes that Plaintiffs have provided an evidentiary basis for the time period outside of Mr. Steifel's employment with Sandoz.

16. For internal business purposes, Sandoz calculated the average sales prices for its products on a regular basis. (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 486:23-487:10, Ex. 42.)

SANDOZ' RESPONSE TO PARAGRAPH 16:

Sandoz disputes the assertion set forth in Paragraph 16 as misleadingly vague and unsupported. The cited testimony refers to a document Mr. Worrell had never seen and Mr. Worrell testified only that average prices might have been calculated periodically for budgeting or to compare to WACs to analyze potential decreases in WAC. Kevin Galownia, Sandoz's former manager of pricing and financial analysis, testified that he did not employ a regular

financial model to evaluate and calculate contract prices. *See* Castaldo Decl. Ex. 21 (03/26/2008 Worrell Dep. at 484:10-14); Castaldo Decl. Ex. 12 (06/11/07 Galownia Dep. at 159:19-161:1). Mr. Galownia further testified that he prepared documents with three month average price calculations to evaluate opportunities to decrease Sandoz' WACs, and that the average prices were calculated across all types of customers. *See* Castaldo Decl. Ex. 12 (06/11/07 Galownia Dep. at 246:5-247:9). Such documents were prepared with "no regular rhyme or reason" and "probably . . . twice a year." *See* Castaldo Decl. Ex. 12 (06/11/07 Galownia Dep. at 250:5-14). Sandoz calculated AMPs on a quarterly basis as required by federal law and provided those AMPs to Medi-Cal for a number of years.

17. Sandoz contracted directly with large retail pharmacy chains (Paul Ex. 7 (11/13/08 Frank Stiefel Dep.), at 107:25-108:25) and group purchasing organizations (Paul Ex. 8 (5/2/08 Wanda Edwards Dep.) at 26:1-5) for the sale of its products.

SANDOZ' RESPONSE TO PARAGRAPH 17:

Undisputed, except Sandoz clarifies that the cited testimony does not support the conclusion that Sandoz contracted directly with all large retailer pharmacy chains or group purchasing organizations, and that group purchasing organizations do not purchase and take possession of Sandoz' products; instead they function as negotiating entities on behalf of their members. *See* Castaldo Decl. Ex. 12 (06/11/07 Galownia Dep. at 379:3-9). Further, the truth or falsity of this statement is not relevant to this Court's determination of summary judgment.

18. Sandoz did not report its transactional prices, nor any average or compilation of these prices, to the pricing compendia or to Medi-Cal as its products' AWP or otherwise. Paul Ex. 6 (1/27/09 Frank Stiefel Dep.), at 379:19-380:7.)

SANDOZ' RESPONSE TO PARAGRAPH 18:

Disputed. Beginning on July 16, 1991, Sandoz voluntarily provided the State of California with its Average Manufacturer Price data. *See* Castaldo Decl. Ex. 23 (Letter from Beth

Brannan, Manager, Government Affairs, Geneva Pharmaceuticals, Inc. (Sandoz) to Michael Neff, California Dept. of Health Services enclosing AMP data, dated July 16, 1991 (SANDOZ CALI 3000033)); *see also* Castaldo Decl. Ex. 24 (Excerpt of June 10, 2009 deposition of Roy Takeuchi (“06/10/09 Takeuchi Dep.”) at 145:3-22). Sandoz continued to directly provide the State of California with its AMP data until March 21, 1997. *See* Castaldo Decl. Ex. 25 (Letter from Ron Hartmann, Manager, Government Affairs, Geneva Pharmaceuticals, Inc. (Sandoz) to State of California enclosing AMP data, dated Mar. 21, 1997 (SANDOZ CALI 3001109)). Sandoz further disputes any inference that Sandoz was required to report mathematical averages of prices to First DataBank or Medi-Cal, or that Medi-Cal or First DataBank expected AWP’s to be actual averages of prices. *See* Castaldo Decl. Ex. 12 (06/11/2007 Galownia Dep. at 113:6-9; 114:6-9; 220:16-221:2); *see also* Response to paragraph 11. Moreover, when collecting AWP’s, First DataBank never told Sandoz that it was expecting actual average prices. *See* Castaldo Decl. Ex. 12 (06/11/2007 Galownia Dep. at 387:15-388:6). In fact, First DataBank told its own customers that AWP was referred to as “ain’t what’s paid.” *See* Castaldo Decl. Ex. 16 (07/20/2009 Donovan Dep. at 355:5-20); Castaldo Decl. Ex. 17 (Donovan Ex. 15 (First DataBank Presentation re: Pricing Methodologies), Bates # HI_HI000002693); Castaldo Decl. Ex. 18 (08/27/2007 Morgan Dep. at 80:11-81:9). Sandoz further disputes that Plaintiffs have provided an evidentiary basis for the time period outside of Mr. Stiefel’s employment with Sandoz, which was from January 2001 to January 2004. *See* Castaldo Decl. Ex. 26 (Excerpt of November 13, 2008 deposition of Frank Stiefel (“11/13/2008 Stiefel Dep.”) at 39:13-21).

19. There was no fixed or predictable relationship between the AWP’s that Sandoz reported to FDB and the prices at which its products were sold to the retail class of trade. (Paul Ex. 3 (6/11/07 Kevin Galownia Dep.), at 169:5-17.)

SANDOZ’ RESPONSE TO PARAGRAPH 19:

Sandoz disputes Paragraph 19 to the extent that it mischaracterizes Mr. Galownia's testimony regarding the relationship between the AWP's that Sandoz reported to First DataBank and the prices at which its products were sold in the retail class of trade. Mr. Galownia explained that WACs were Sandoz' invoice price to wholesalers and were published. WACs represented the highest selling price for Sandoz' products sold directly from Sandoz to wholesalers and/or the retail class of trade, but discounts and rebates could lower prices received by Sandoz below WAC. *See* Castaldo Decl. Ex. 21 (03/26/08 Worrell Dep. at 331:6-332:6); Castaldo Decl. Ex. 27 (Excerpt of June 5, 2008 deposition of Richard Rogerson ("06/05/2008 Rogerson Dep.") at 130:7-131:16). AWP's were always higher than WAC, consistent with Sandoz' understanding of industry practices. *See* Castaldo Decl. Ex. 21 (03/26/08 Worrell Dep. at 332:7-13). Sandoz did not know the prices between wholesalers and retailers. *See* Castaldo Decl. Ex. 21 (03/26/08 Worrell Dep. At 383:3-5; 401:12-17); Castaldo Decl. Ex. 12 (06/11/07 Galownia Dep. at 375:7-376:19). Sandoz further disputes that Plaintiffs have provided an evidentiary basis for the time period outside of Mr. Worrell's employment with Sandoz.

D. Sandoz's Knowledge of Medicaid and Medi-Cal Policies

20. Sandoz was aware of or on notice of Medicaid and Medi-Cal reimbursement policies in general. (Paul Ex. 7 (11/13/08 Frank Stiefel Dep.), at 70:14-25; Paul Ex. 9 (5/6/09 Ronald Hartmann Dep.), at 330:21-332:14.)

SANDOZ' RESPONSE TO PARAGRAPH 20:

Sandoz disputes Paragraph 20 to the extent that it mischaracterizes the testimony of Mr. Stiefel and Mr. Hartmann regarding Sandoz' awareness of Medi-Cal's reimbursement practices throughout the relevant time period. Mr. Hartmann, Sandoz' Director of Government Affairs, testified that it was his belief that Medi-Cal used numerous tools to calculate reimbursements to providers, including FULs and MACs. *See* Castaldo Decl. Ex. 15 (05/06/09 Hartmann Dep. at

331:19-332:4. It is undisputed that Sandoz set prices for its products without reference to California's reimbursement policies and practices. *See* Castaldo Decl. Ex. 19 (06/19/2008 Galownia Dep. at 237:6-18; 37:10-14; 68:14-70:1); Castaldo Decl. Ex. 13 (08/23/2007 Worrell Dep. at 60:23-61:7; 67:18-68:1; 123:7-9). Mr. Steifel did not have responsibility for any work in connection with Medicaid, and no foundation was provided for his testimony. *See* Castaldo Decl. Ex. 28 (Excerpt of January 27, 2009 deposition of Frank Stiefel ("01/27/2009 Stiefel Dep.") at 481:10-15). Moreover, Sandoz only participates in Medicaid at the federal level, through the rebate program, and its obligations thus are spelled out in federal law and the rebate agreement. *See* Castaldo Decl. Ex. 12 (06/11/07 Galownia Dep. at 67:17-68:6). Sandoz is not a Medi-Cal provider and not required to be aware of Medi-Cal's reimbursement practices.

21. Sandoz was aware of or on notice that Medi-Cal reimbursed providers for pharmaceutical products based on the reported AWP of the products. (Paul Ex. 9 (5/6/09 Ronald Hartmann Dep.), at 330:21-332:14.)

SANDOZ' RESPONSE TO PARAGRAPH 21:

Sandoz disputes Paragraph 21 to the extent that it creates the false impression that Sandoz was aware that Medi-Cal reimbursed providers based solely on the reported AWP of the products. Mr. Hartmann, Sandoz' Director of Government Affairs, testified that it was his belief that Medi-Cal used numerous tools to calculate reimbursements to providers, including FULs and MACs. *See* Castaldo Decl. Ex. 15 (05/06/09 Hartmann Dep. at 331:19-332:4). Furthermore, it is undisputed that Sandoz set prices for its products without reference to California's reimbursement policies and practices. *See* Castaldo Decl. Ex. 19 (06/19/2008 Galownia Dep. at 237:6-18; 37:10-14; 68:14-70:1; 80:22-82:2); Castaldo Decl. Ex. 13 (08/23/2007 Worrell Dep. at 60:23-61:7; 67:18-68:1; 123:7-9). Sandoz also disputes Paragraph 21 to the extent that it misstates the reimbursement methodology employed by California, which uses multiple

measures for determining reimbursements to providers, only one of which is calculated using discounted AWP. *See e.g.*, CAL. CODE REGS. tit. 22, § 51513 (2002); CAL. WELF. & INST. CODE § 14105.45 (2004).

E. Claims Submitted For All of Sandoz's Subject Drugs Were Materially False.

22. Plaintiffs' expert, Dr. Leitzinger, used data provided by Sandoz to estimate the average prices paid by pharmaceutical wholesaler's customers [i.e., providers] for each of the 149 relevant Sandoz NDCs. Dr. Leitzinger did that by calculating the prices that wholesalers paid to Sandoz for each NDC and then applying a wholesaler markup to those prices to estimate the total amount that customers paid to wholesalers for each such NDC. (Paul Ex. 10 (Leitzinger Decl.), at ¶ 4). His methodology is explained more fully at paragraphs 12-20 of his Report, which is attached as Ex. A to his Declaration. The wholesaler markup that Dr. Leitzinger used was based on data contained in the "Industry Profile and Healthcare Factbook," published by the Healthcare Distribution Management Association. That markup ranged over time between 3.7 percent and 5.4 percent. (Paul Ex. 10 (Leitzinger Decl.), Ex. A at ¶ 20, n.20.)

SANDOZ' RESPONSE TO PARAGRAPH 22:

Sandoz does not dispute Plaintiffs' description of the means by which Dr. Leitzinger calculated his estimate of average prices paid by pharmaceutical wholesalers' customers (also known as net quarterly prices) for the Sandoz NDCs at issue in this case. However, Sandoz disputes that these findings, the substance of which Sandoz contests, constitute "undisputed facts" appropriate for a 56.1 statement and that these calculations provide any relevant information. The methodologies employed by Dr. Leitzinger and the conclusions derived therefrom are fundamentally flawed and lack any credible basis. For example, Dr. Leitzinger's use of a wholesaler mark-up between 3.7 percent and 5.4 percent to determine the averages prices paid by wholesalers' customers for NDCs is incorrect because it substantially understates wholesale margins for generic drugs and has not connection to the facts of this case, rendering both incorrect and inadmissible. *See* Castaldo Decl. Ex. 29 (Expert Report of Daniel L. Rubinfeld ("Rubinfeld Report") at ¶¶ 131-34); Castaldo Decl. Ex. 21 (03/26/08 Worrell Dep. at

404:17-405:18). Dr. Letizinger's calculations, moreover, start with the predicate that California would have changed its reimbursement formula, and did not involve any investigation that the averages he calculated would have or could have been used by Medi-Cal, or whether they would have been acceptable reimbursement levels to retail providers. *See* Castaldo Decl. Ex. 30 (Excerpts of September 24, 2009 deposition of Jeffrey Leitzinger ("09/24/09 Leitzinger Dep.") at 371:16-372:22; 408:17-410:5; 455:11-456:19; 504:14-505:2). Furthermore, Dr. Leitzinger's calculations of net quarterly prices for 1994 and 1995 (years for which Dr. Leitzinger had no Sandoz transaction data) are flawed to the extent that he has used an exaggerated "overcharge ratio" used to derive these prices. *See* Castaldo Dec. Ex. 29 (Rubinfeld Report at ¶¶ 135-36). Finally, Dr. Leitzinger's opinion relies on the Healthcare Distribution Management Association, which is inadmissible hearsay.

23. Ex. 4 to Dr. Leitzinger's Report shows in column (6) the "spread" (the difference between the average net quarterly prices that he calculated and the reported AWP) for each of the 149 relevant Sandoz NDCs on a quarter-by-quarter basis from the first quarter of 1994 through the fourth quarter of 2004. (Paul Ex. 10 (Leitzinger Decl.), at ¶ 5.)

SANDOZ' RESPONSE TO PARAGRAPH 23:

Sandoz does not dispute Plaintiffs' description of the means by which Dr. Leitzinger calculated and presented the "spread" (defined by Plaintiff as the "difference between the average net quarterly prices that he calculated and the reported AWP") for each of the Sandoz NDCs at issue in this case. However, Sandoz disputes that these findings, the substance of which Sandoz contests, constitute "undisputed facts" appropriate for a 56.1 statement and that these calculations provide any relevant information. . The methodologies employed by Dr. Leitzinger and the conclusions derived therefrom are fundamentally flawed and lack any credible basis. For example, Sandoz' expert has contradicted the method by which Dr. Leitzinger arrived at his net quarterly prices for the NDCs at issue. *See* Castaldo Decl. Ex. 29 (Rubinfeld Report at

¶¶ 131-36). Sandoz further disputes as misleading Dr. Leitzinger's use of AWP in making any comparisons, as California did not reimbursement providers at AWP. *See e.g.*, CAL. CODE REGS. tit. 22, § 51513 (2002); CAL. WELF. & INST. CODE § 14105.45 (2004). Dr. Letizinger's calculations, moreover, start with the predicate that California would have changed its reimbursement formula, and did not involve any investigation that the averages he calculated would have or could have been used by Medi-Cal, or whether they would have been acceptable reimbursement levels to retail providers. *See* Castaldo Decl. Ex. 30 (09/24/09 Leitzinger Dep. at 371:16-372:22; 408:17-410:5; 455:11-456:19; 504:14-505:2).

24. For over 95 percent of the Sandoz NDC/quarter combinations for which he had complete data, the AWP reported by Sandoz exceeded the average net quarterly prices paid by wholesalers' customers by at least 100 percent. For 82 percent of those NDC/quarter combinations, the spread exceeded 300 percent, with some greater than 2,000 percent. (Paul Ex. 10 (Leitzinger Decl.), at ¶ 6.)

SANDOZ' RESPONSE TO PARAGRAPH 24:

Sandoz does not dispute Plaintiffs' description of the means by which Dr. Leitzinger calculated the percentage by which AWP exceeded net quarterly price for the Sandoz NDCs at issue in this case. However, Sandoz disputes that these findings, the substance of which Sandoz contests, constitute "undisputed facts" appropriate for a 56.1 statement and that these calculations provide any relevant information. The methodologies employed by Dr. Leitzinger and the conclusions derived therefrom are fundamentally flawed and lack any credible basis. Dr. Leitzinger's conclusions as to the difference between AWP and net quarterly price are particularly irrelevant because the State of California did not reimburse on the basis of AWP for a majority of the NDCs at issue, and reimbursed instead on the basis of Federal Allowable Cost (FAC). *See* Castaldo Decl. Ex. 29 (Rubinfeld Report at ¶¶ 43; 120-130). Dr. Leitzinger's calculations, moreover, start with the predicate that California would have changed its

reimbursement formula, and did not involve any investigation that the averages he calculated would have or could have been used by Medi-Cal, or whether they would have been acceptable reimbursement levels to retail providers. *See* Castaldo Decl. Ex. 30 (09/24/09 Leitzinger Dep. at 371:16-372:22; 408:17-410:5; 455:11-456:19; 504:14-505:2).

25. For purposes of calculating the overpayments made by the State for the 149 relevant Sandoz NDCs, Dr. Leitzinger excluded claims for which the actual reimbursement did not exceed the average net price paid by wholesalers to Sandoz by at least 25 percent. For each remaining claim, he calculated the difference between the actual ingredient cost reimbursed by the State and an amount 25 percent above the average net price paid by wholesalers to Sandoz. That difference was the overpayment he found. (Paul Ex. 10 (Leitzinger Decl.), at ¶ 7.)

SANDOZ' RESPONSE TO PARAGRAPH 25:

Disputed. Dr. Leitzinger's analysis, the substance of which Sandoz disputes and which does not constitute "undisputed facts" appropriate for a 56.1 statement, does not calculate an "overpayment," but instead calculates a difference between two sets of numbers based on numerous assumptions provided by plaintiffs' counsel that are not supported by the facts in this case. *See* Castaldo Decl. Ex. 30 (09/24/09 Leitzinger Dep. at 371:16-372:22). The methodologies employed by Dr. Leitzinger and the conclusions derived therefrom are fundamentally flawed and lack any credible basis. Dr. Leitzinger provides no explanation or economic justification for his use of a 25% margin threshold to determine the NDCs for which the State had overpaid. *See* Castaldo Decl. Ex. 29 (Rubinfeld Report at ¶¶ 105-108). Furthermore, Dr. Leitzinger's assumption that any "spread" of 25% or more constitutes an overpayment by the State is faulty because it fails to evaluate whether Medi-Cal would have or could have reimbursed at that level, given the need, for example, to maintain access and cover losses on dispensing fees. *See* Castaldo Decl. Ex. 29 (Rubinfeld Report at ¶¶ 113-116); Castaldo Decl. Ex. 30 (09/24/09 Leitzinger Dep. 455:11-456:19).

F. Sandoz Acted Knowingly in Making the Above False Statements.

26. Sandoz did not define AWP as a price paid by retailers to wholesalers for its products. Instead, AWP was a price set by Sandoz only to ensure a generic designation from the pricing entities, such as FDB. (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 383:21-384:9.)

SANDOZ' RESPONSE TO PARAGRAPH 26:

Sandoz does not dispute that, during the relevant time period, Sandoz did not define AWP as a price paid by retailers to wholesalers for its products. Instead, Sandoz set its AWP in a manner consistent with industry practice. *See* Castaldo Decl. Ex. 19 (06/19/2008 Galownia Dep. at 237:6-18). Sandoz also set its AWP as a result of interactions with First DataBank. *See* Castaldo Decl. Ex. 19 (06/19/2008 Galownia Dep. at 37:10-14; 68:14-70:1); Castaldo Decl. Ex. 13 (08/23/2007 Worrell Dep. at 60:23-61:7; 67:18-68:1; 123:7-9). Sandoz' understanding of AWP thus was consistent with the use and understanding of AWP at Medi-Cal, the federal government and First DataBank, among others.

Dated: December 21, 2009

By: /s/ Wayne A. Cross

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CERTIFICATE OF SERVICE

I, Daniel Cohen, hereby certify that on December 21, 2009, I have caused true and correct copies of the foregoing Defendant Sandoz Inc.'s Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Facts as to Sandoz Inc. to be served on all counsel of record by electronic service, pursuant to the Case Management Order No. 2 entered in by Honorable Patti B. Saris in MDL 1456.

_____/s/ Daniel Cohen
Daniel Cohen